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15 **UNITED STATES DISTRICT COURT**
16 **CENTRAL DISTRICT OF CALIFORNIA**
17 **SOUTHERN DIVISION**

18 PURECIRCLE USA INC. and
19 PURECIRCLE SDN BHD,

20 Plaintiffs,

21 v.

22
23 SWEEGEN, INC. and PHYTO TECH
24 CORP. d/b/a BLUE CALIFORNIA,

25 Defendants.

CASE NO. 8:18-CV-01679-JVS-JDE

**PURECIRCLE'S MEMORANDUM
OF POINTS AND AUTHORITIES
IN OPPOSITION TO SWEEGEN'S
MOTION FOR PARTIAL
SUMMARY JUDGMENT OF
INVALIDITY AND CROSS-
MOTION FOR SUMMARY
JUDGMENT ON WRITTEN
DESCRIPTION**

Date: April 11, 2022
Time: 1:30 p.m.
Room: 10C
Judge: The Hon. James V. Selna

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs PureCircle USA Inc. and PureCircle SDN BHD (collectively, "PureCircle") respectfully request that the Court deny Defendants SweeGen, Inc.'s and PhytoTech Corp. d/b/a Blue California's (collectively, "SweeGen") motion for summary judgment of invalidity. SweeGen's Opening Brief (Dkt. 179-1) repeats arguments that were already reviewed and firmly rejected by the Patent Office in connection with either prosecution of, or SweeGen's own post-grant challenges to, the asserted patents. These arguments fare no better upon repetition, and fall far short of satisfying SweeGen's burden to prove patent invalidity by clear and convincing evidence. SweeGen's invalidity arguments are contrary to Federal Circuit precedent, highlight disputed issues of fact that preclude summary judgment, and ignore Patent Office findings of fact that are contrary to those that SweeGen now contends are undisputed.

SweeGen's argument that the claims in the '273 and '257 Patents are not patent eligible under 35 U.S.C. § 101 on grounds that they purportedly capture a natural phenomenon fail as a matter of law for at least two reasons. First, instead of analyzing "the claim as a whole," as required by the Supreme Court and Federal Circuit authority that even SweeGen cites, SweeGen ignores several independent and dependent claim limitations in its analysis. For example, SweeGen's § 101 step-one analysis disregards the "recombinant biocatalyst protein enzyme" limitation in claim 1 of the '257 Patent, and the "conversion of Rebaudioside D to Rebaudioside X is at least about 50% complete" limitation in claim 1 of the '273 Patent, neither of which do or can occur naturally. When those claim limitations (and others) are considered as part of the § 101 analysis, the claims of the '273 and '257 Patent cannot be considered natural phenomena because, among other reasons, the claims use a process to prepare Rebaudioside M at high conversion (and purity) not available in nature. Second, SweeGen's argument relies on inapposite cases directed

1 to diagnostic patents in which the invention at issue reflected the discovery of a
2 natural phenomenon itself. That is very different from the method-of-preparation
3 claims in the '273 and '257 Patents, which concern a human-engineered process for
4 producing Rebaudioside M that is very different from any process that occurs
5 naturally in the *Stevia rebaudiana* plant. Recent controlling case law directed to
6 similar method-of-preparation claims confirms that SweeGen cannot as a matter of
7 law show that the '273 and '257 Patents' claims are ineligible under 35 U.S.C. §101.

8 SweeGen's arguments based on the written description requirement (35
9 U.S.C. §112) should also be rejected. SweeGen's motion never addresses—much
10 less disputes—the original-claim doctrine, which confirms that the claims of the
11 '273 and '257 Patents (the subject matter of which was included in PureCircle's
12 originally filed claims) satisfy the written description requirement. Nor does
13 SweeGen mention that the Patent Trial and Appeal Board ("PTAB") has already
14 rejected SweeGen's nearly-identical written description arguments in denying
15 institution of SweeGen's petition for Post-Grant Review ("PGR") regarding the '257
16 Patent, or that the PTAB specifically found that the claims of the '257 Patent (which
17 shares the same specification as the '273 Patent) satisfied the written description
18 requirement. (PAMF¹ 10.) SweeGen's failure to succeed on these arguments even
19 under the lower burden of proof applicable to PGR proceedings confirms that
20 SweeGen's argument cannot succeed under the higher clear and convincing
21 evidence standard applicable to SweeGen's motion for summary judgment.
22 SweeGen's argument that PureCircle was required to describe all potential
23 embodiments (including future embodiments and materials) is also contrary to the
24 law and common sense. Not only should SweeGen's motion be denied, but the Court
25 should grant summary judgment that the claims of the '257 Patent and the '273
26

27 ¹ Citation are to PureCircle's Additional Material Facts (PAMF) appearing in
28 PureCircle's L.R. 56-2 Statement of Genuine Disputes, or to PureCircle's PSUF
numbers in PureCircle's L.R. 56-1 Statement of Unconverted Facts.

1 Patent satisfy the written description requirement.

2 Finally, SweeGen's motion for summary judgment regarding enablement
3 should be denied for at least two reasons. First, SweeGen applies an incorrect legal
4 standard and ignores that the enablement requirement is met if the specification
5 enables any mode of making and using the invention. SweeGen fails to offer
6 evidence proving that a person of ordinary skill in the art would be unable to make
7 Rebaudioside M using the patent disclosure, and PureCircle's expert has articulated
8 facts and opinions that preclude summary judgment on enablement. SweeGen's
9 argument that the specification must disclose every possible way of carrying out the
10 invention, including ways not even available at the time of filing of the patent, is
11 contrary to the law. Second, there are multiple disputed facts related to the eight-
12 factor *Wands* test that governs the enablement inquiry, and SweeGen's attorney
13 argument does not and cannot resolve those factual disputes.

14 The PTAB applied the *Wands* factors in addressing SweeGen's nearly
15 identical enablement argument during the PGR proceedings regarding the '257
16 Patent, and found that SweeGen failed to demonstrate even a "more likely than not"
17 chance of prevailing on that issue. (PAMF 11.) For those same reasons articulated
18 by the PTAB, SweeGen cannot demonstrate that the claims are invalid under the
19 higher clear and convincing evidence standard applicable in this lawsuit. Having
20 previously represented to the Court that the PTAB proceedings would narrow the
21 issues in this litigation when seeking to stay this case (*see* Dkt. 117 at 8-11),
22 SweeGen ignores the PTAB ruling to take a second bite at the apple using the same,
23 already rejected arguments, inconsistent with its promises to "narrow the issues,
24 obtain guidance from the PTO, or simply [] avoid the needless waste of judicial
25 resources." Dkt. 117 at 8-11. And while SweeGen is not legally estopped from
26 asserting its written description and enablement defenses, the PTAB's rejection of
27 these same arguments under a lower standard of proof only underscores that
28 SweeGen has fallen far short of its burden to prove that summary judgment should

1 be granted.² The Court's should deny SweeGen's motion on all issues.

2 **II. THE CLAIMS ARE PATENT-ELIGIBLE SINCE THEY INCLUDE**
3 **MANY CLAIM LIMITATIONS THAT NEVER OCCUR IN NATURE**

4 **A. When the Claims are Analyzed as a Whole, Several Claim**
5 **Limitations Are Not And Cannot Be Found In Nature**

6 The Supreme Court has set forth a two-step test for determining whether a
7 patent is directed to an unpatentable idea. *Alice Corp. v. CLS Bank Int'l*, 573 U.S.
8 208 (2014). First, the court must determine "whether the claims at issue are directed
9 to a patent-ineligible concept," such as a natural phenomenon. *Id.* at 218. Second, if
10 the claims are directed to an ineligible concept, the court must decide whether there
11 is an "inventive concept" in the claims. *Id.* at 221. As the cases SweeGen cites state,
12 "[t]he step one 'directed to' inquiry focuses on *the claim as a whole*." *Athena*
13 *Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 705 (Fed. Cir.
14 2019) (emphasis added).³ Instead of examining the *whole* claim as required under §
15 101, SweeGen ignores key limitations in the claims to arrive at the conclusion that
16 the claims of the asserted patents are directed to natural phenomena. When these
17 limitations are considered—as they must be—SweeGen cannot satisfy its burden to
18 establish that the claims of the '257 Patent are directed to natural phenomena.

19 **1. The '257 Patent Does Not Claim A Natural Phenomena**

20 The undisputed facts in this case prove that '257 Patent claim 1 is a method of
21 preparation of Rebaudioside M that does not and cannot exist in nature, as
22 confirmed by SweeGen's own expert, Dr. Jacqueline Gervay-Hague.

23
24 ² See *Precision Fabrics Grp., Inc. v. Tietex Int'l, Ltd.*, 2016 WL 6839394, at *9
25 (M.D.N.C. Nov. 21, 2016) ("PTAB's refusal to institute ... is indicative of the
26 weakness of TieTex's claim of invalidity ... "); *Ultratec, Inc. v. Sorenson Commc'ns,*
27 *Inc.*, 2015 WL 5330284, at *14 (W.D. Wis. Sept. 11, 2015) ("This court is not
28 bound by the PTAB decision [denying institution], but its reasoning is persuasive.").

³ See also *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 90
(2012) ("[P]atent claims 'must be considered as a whole,'" quoting *Diamond v.*
Diehr, 450 U.S. 175, 188 (1981)).

1 The Court has defined "recombinant biocatalyst protein enzyme" as "a protein
2 enzyme made from a gene that has been cloned and introduced into an expression
3 system." As Dr. Gervay-Hague explained in her deposition, *Stevia rebaudiana*
4 plants do not introduce genes into an expression system, and certainly do not clone
5 foreign genes into an expression system. (PAMF 12.) As PureCircle's expert, Dr.
6 Bollinger stated: "In nature, microorganisms are not usually hijacked by humans to
7 serve as machines for making valuable chemicals." (PAMF 13.) Thus, a process of
8 making Rebaudioside M by using a recombinant biocatalyst protein enzyme as
9 claimed in claim 1 of the '257 Patent simply cannot occur in nature.

10 SweeGen disregards the "recombinant biocatalyst protein enzyme" limitation
11 of claim 1 in its step-one analysis, treating it as an afterthought only in its step-two
12 analysis. Dkt. 179-1 at 7-8 (SweeGen fails to address the "recombinant biocatalyst
13 protein enzyme" limitation in its step-one analysis). Moreover, SweeGen's assertion
14 that there is no "dispute that the biocatalytic conversion reaction claimed in the '257
15 patent—converting a steviol glycoside to Reb M using UDP-glucosyltransferase—is
16 the same process that occurs in nature" is both unsupported and untrue. Dkt. 179-1
17 at 7. The claimed method in the '257 patent—which requires a recombinant
18 enzyme—**does not and cannot occur in nature**. Not only does SweeGen fail to cite
19 any evidence supporting its argument, but Dr. Gervay-Hague (SweeGen's expert),
20 Dr. Bollinger (PureCircle's expert), and Dr. Oliver Yu (SweeGen's own Chief
21 Science Officer) *all* disagree with SweeGen's statement.

22 As Dr. Yu explained in his deposition, in the *Stevia rebaudiana* plant that
23 occurs in nature, it is impossible to make significant amounts of Rebaudioside M
24 because the plant not only includes enzymes that add glucose to rebaudiosides, but
25 also many enzymes that remove glucose from the rebaudiosides. (PAMF 59.)
26 Indeed, there is such a mixture of enzymes in the plant that "[y]ou don't get much of
27 the Rebaudioside D, Rebaudioside M, Rebaudioside D4, and all these compounds."
28 (*Id.* 83:14-16.) While it is true that trace amounts of Rebaudioside D and

1 Rebaudioside M have been found in plants, "the quantity are very, very small"
2 (*Id.* 83:16-20.) [REDACTED]

3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED] (PAMF 60 at
9 SGB00215813.) That alternative production method using a recombinant enzyme
10 developed by humans is precisely what is claimed in the '257 Patent. SweeGen's
11 motion fails to address its own admissions showing the claimed recombinant-
12 enzyme process in the '257 Patent differs significantly from the plant process.

13 Indeed, Dr. Bollinger describes five additional material differences between
14 the process in the plant and the '257 Patent's claimed recombinant-enzyme process,
15 including the fact that there is limited contact between the *non*-recombinant
16 enzymes in the plant and the steviol glycoside substrates (contact is required by the
17 claims), and also the same differences that Dr. Yu discussed in his deposition
18 between the recombinant-enzyme process and the other enzymes and reactions that
19 occur naturally in the plant. (PAMF 18.) SweeGen's motion does not even mention
20 Dr. Bollinger's analysis, and SweeGen has proffered no rebuttal to it.

21 In its very thin discussion of step one, SweeGen also discusses "the claimed
22 'biocatalytic process'" and the meaning of "biocatalytic process" in the specification.
23 Dkt. No 179-1 at 7. But there is no claimed "biocatalytic process." "Biocatalytic
24 process" appears nowhere in either Patent's claims, and SweeGen's discussion is
25 irrelevant to whether the claims are directed to a natural phenomenon.

26 SweeGen also quotes Dr. Bollinger, who testified that non-prior-art literature
27 written by PepsiCo *after* the filing date of the PureCircle asserted patents shows that
28 recombinantly generated wild-type UGT76G1 will convert Rebaudioside E to

1 Rebaudioside M. Dkt. 179-1 at 8. It is not apparent why this testimony has any
2 relevance to whether the patent claims cover a natural phenomenon. There is no
3 dispute that UDP-glucosyltransferases occur in nature, that these natural enzymes
4 can also be generated recombinantly, and that those recombinant enzymes that are
5 not mutants are referred to as "wild-types." But nature cannot generate recombinant
6 UDP-glucosyltransferases produced by host microorganisms of the PureCircle
7 patents (*see, e.g.*, claims 6 and 7 of the '257 Patent), nor use isolated systems where
8 the Rebaudioside M conversion is significant as set forth in the claims of the
9 PureCircle patents ((*see, e.g.*, claims 1 and 7-11 of the '273 Patent), and Drs.
10 Bollinger, Gervay-Hague, and Yu all agree that nature does not do so.

11 Claims 3, 4 and 5 of the '257 Patent further require a process to prepare
12 purified Rebaudioside M that is not available in nature. Although SweeGen
13 dismisses these claims with no analysis (*see* Dkt. 179-1 at 8 (arguing that "[n]one of
14 these additional limitations alters the fact that these claims are directed to naturally
15 occurring processes")), both parties' experts in this case believe otherwise. Indeed,
16 both Dr. Gervay-Hague and Dr. Bollinger testified that a process of preparing
17 purified Rebaudioside M does not occur in nature. Specifically, Dr. Gervay-Hague
18 testified that plants do not purify Rebaudioside M, and that there is no purified
19 Rebaudioside M inside of plants, because the trace amount of Rebaudioside M in a
20 plant is "going to be, you know, along with everything else that's in the plant."
21 (PAMF 22.) And Dr. Bollinger testified that to get the high levels of purity required
22 by claims 3-5 of the '257 Patent (and claims 4-6 of the '273 Patent), one needs a
23 larger quantity of Rebaudioside M than can be obtained from the plant. (PAMF 23.)
24 In short, the purity levels required in the dependent claims of the PureCircle patents
25 are not present or available naturally.

26 Claims 6 and 7 of the '257 Patent further require that the enzymes must be
27 expressed in a host microorganism, such as the bacteria *E. coli* or the fungi
28 *Saccharomyces*, *Aspergillus*, or *Pichia*. These microorganisms identified in the

1 claims do not produce the claimed enzymes in nature, but only when they are
2 bioengineered by humans to do so. (PAMF 25.) And Dr. Gervay-Hague testified
3 that there is no evidence that these microorganisms, if even present in *Stevia*
4 *rebaudiana* plants, are making UDP-glucosyltransferases that are capable of
5 transferring a glucose to a steviol glycoside as required by the claims of the '257
6 Patent. (PAMF 27.) Thus, SweeGen has failed to provide evidence that the claimed
7 bioengineered host microorganisms in claims 6 and 7—which carry out a process
8 that they would never carry out without significant human manipulation and cloning
9 techniques—are a natural phenomenon that are not eligible for patent protection.

10 **2. The '273 Patent Does Not Claim A Natural Phenomena**

11 As with the '257 Patent, SweeGen's § 101 arguments regarding the '273 Patent
12 claims fail to consider the claims *as a whole*. Claim 1 of the '273 Patent requires that
13 the "conversion of Rebaudioside D to Rebaudioside X [M] is at least about 50%
14 complete...." As SweeGen's Dr. Yu explained, it is impossible to reach this
15 conversion level naturally in the plant. (PAMF 15.) And Dr. Bollinger also
16 explained that a natural process cannot reach the 50% conversion level required by
17 claim 1, and that only a man-made process (such as a process using a recombinant
18 enzyme) can achieve the high level of purity required by the claims. (PAMF 28; *see*
19 *also* PAMF 24.) Of course, the same is true regarding dependent claims 7-11 of the
20 '273 Patent, all of which require even higher conversion levels than the 50% level
21 set forth in claim 1. (*Id.*) There is no evidence indicating that conversion levels
22 required by the claims of the '273 Patent occur in nature. SweeGen's motion should
23 be denied for that reason alone.

24 Instead of citing evidence establishing that a 50% conversion to Rebaudioside
25 M occurs naturally in the *Stevia rebaudiana* plant, SweeGen argues without
26 evidence that the plant naturally makes Rebaudioside M and "that the conversion of
27 Reb D to Reb M is at least about 50% complete ... does not alter the focus of the
28 claims" Dkt. 179-1 at 13-14. SweeGen's misleading argument and approach only

underscore that its § 101 step-one analysis fails to consider the claim as a whole. The conversion requirements are limitations of the claim, and both Dr. Yu and Dr. Bollinger agree that those requirements do not and cannot occur naturally.

Indeed, the USPTO examiner expressly considered the § 101 issue during prosecution of the '273 Patent, and allowed the claims. Significantly, the examiner rejected an earlier version of claim 1 of the '273 Patent that did *not* contain the "wherein the conversion of Rebaudioside D to Rebaudioside X is at least about 50% complete" limitation. (*See* PAMF 29.) However, the examiner subsequently found the claims eligible under § 101 after that conversion requirements was added to claim 1 via amendment. (PAMF 30.) Thus, the USPTO examiner who allowed the claims of the '273 Patent explicitly considered the § 101 issue, and rejected SweeGen's position in this litigation that the claims are ineligible.

SweeGen's motion references citations to its Statement of Uncontested Facts ("SUF"), but those citations do not support the arguments SweeGen makes in its motion. For example, SweeGen's SUF 35 (Dkt. 179-2 at 13) states that "the conversion of Reb D to Reb M by UGT76G1 is a naturally occurring phenomenon," but that fails to address the key fact that the conversion in the plant is minimal and nowhere close to the 50% conversion required by claim 1 of the '273 Patent, much less the higher conversion levels required by claims 7-11. SUF 39 (Dkt. 179-2 at 14) quotes Dr. Bollinger's testimony (PAMF 28) in which he explains that only a human-made method of producing Rebaudioside M can achieve a 50% conversion level—that testimony supports PureCircle's position, not SweeGen's. SweeGen also quotes Dr. Bollinger's report where he refers to PepsiCo's 2019 patent application that describes a human-engineered process for making Rebaudioside M using a recombinant UGT76G1 enzyme (SUF 38 & 40, PAMF 31 (repeating the statements in Bollinger Opening Rpt. ¶ 258 & reviewing the statements at Opening Rpt. ¶ 258, Reply Rpt. ¶ 174-75)), but SweeGen never explains how or why that patent application has any relevance to the process that occurs naturally in plants. Indeed,

1 the fact that PepsiCo's application requires a recombinant enzyme is strong evidence
2 that a 50% conversion rate does *not* occur in nature. (PAMF 31.)

3 Finally, SweeGen mischaracterizes the record by relying on SUF 116 (Dkt.
4 179-2 at 43-45) to contend that Dr. Bollinger admitted that conversion in the plant
5 was 100%. Dkt. 179-1 at 14. The testimony SweeGen cites says nothing of the sort.
6 Instead, the testimony cited in SUF 116 concerns the '257 Patent's claim 1, not the
7 process in the plant, and does not even address the conversion limitation at issue.
8 (Dkt. 179-2 at 43-45, PAMF 32.) Indeed, Dr. Bollinger stated in his deposition that
9 this testimony concerns claim 1 of the '257 patent. (PAMF 32.). When Dr. Bollinger
10 was asked about the '273 Patent's claim 1, he disagreed with SweeGen's suggestion
11 that the claims somehow cover significant conversion. (PAMF 33.) In short,
12 SweeGen presents no evidence that claim 1's, or the dependent claims' higher
13 conversions of 60, 70, 80, 90, and 95% (claims 7-11), could be found in nature.
14 Indeed, any such finding that these higher conversion levels are a natural
15 phenomenon would be inconsistent with Dr. Yu's testimony that the stevia plant can
16 only make "very, very small" amounts of Rebaudioside M. (PAMF 16.)

17 The remaining dependent claims of the '273 Patent have additional limitations
18 that do not occur naturally, and preclude summary judgment of ineligibility under §
19 101 for additional reasons. Specifically, SweeGen's own expert, Dr. Gervay-Hague,
20 admits that the purification process (claims 4-6) (PAMF 27) and bioengineered host
21 processes (claims 12-13) in the claims do not exist in nature, (*id.*). SweeGen's
22 analysis of these claim limitations (Dkt. 179-1 at 17 citing SUFs Nos. 48, 49, 60,
23 and 62) is wholly deficient, and fails to prove by clear and convincing evidence that
24 the claims of the '273 Patent are directed to a naturally occurring process.

25 *****

26 The claims of the '273 and '257 Patents include several claim limitations that
27 do not occur in nature. Specifically, the recombinant enzyme (claim 1 of the '257
28 Patent), conversion levels (claims 1 and 7-11 of the '273 Patent), purification

1 process (claims 3- 5 of the '257 Patent and claims 4-6 of the '273 Patent), and host
2 microorganism (claims 6-7 of the '273 Patent and claims 12-13 of the '273 Patent)
3 claim limitations do not and cannot occur in the natural process of producing
4 Rebaudioside M. The processes set forth in the claims of the '273 and '257 Patents
5 are different from the process that occurs in the *Stevia rebaudiana* plant, and when
6 the claims are considered as a whole, SweeGen cannot satisfy its burden to
7 demonstrate by clear and convincing evidence that the claims are ineligible for
8 patent protection under § 101. SweeGen's motion should be denied.

9 **B. Case Law Addressing Methods Of Preparation Like Those In The**
10 **Patents Confirms That The Claims Are Patent-Eligible**

11 SweeGen's motion also misstates the law and fails to cite the most relevant
12 Federal Circuit cases addressing the type of method-of-preparation claims at issue
13 here. In those cases, the Federal Circuit drew a key distinction between a "method of
14 preparation case," like the claims at issue here, and a "diagnostic case," like the
15 claims at issue in the cases SweeGen cited. *Illumina, Inc. v. Ariosa Diagnostics*, 967
16 F.3d 1319, 1325 (Fed. Cir. 2020) ("This is not a diagnostic case. And it is not a
17 method of treatment case. It is a method of preparation case."); *Rapid Litig. Mgmt*
18 *Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1049 (Fed. Cir. 2016) Here, the inventors
19 developed an innovative method The claims are thus distinguishable from those
20 held unpatentable in *Myriad*."). Thus, in contrast to claims directed to diagnostics,
21 method-of-preparation claims like the '273 and '257 Patents' claims are usually
22 found to be patent-eligible. *Illumina*, 967 F.3d at 1325-29; *CellzDirect*, 827 F.3d at
23 1048-50.⁴ Indeed, *Illumina*, *CellzDirect*, and district court cases addressing method-

24 _____
25 ⁴ See also *Trustees of Purdue Univ. v. Omron Corp.*, 505 F. Supp. 3d 808, 814 (N.D.
26 Ill. 2020) ("[I]n the medical or biological context, the Federal Circuit has held that
27 patents that create or improve upon useful processes are not 'directed to' abstract
28 ideas under *Alice* step one.... [T]he '611 Patent claims at issue here do not simply
describe a method for observing or detecting a natural phenomenon. Instead, they

1 of-preparation claims all distinguish the diagnostic and other inapplicable cases
2 cited by SweeGen in its brief. *Illumina*, 967 F.3d at 1325-27 (distinguishing *Athena*
3 *Diagnostics*, *Ariosa Diagnostics*, and *Myriad Genetics*); *CellzDirect*, 827 F.3d at
4 1048-49 (same); *Abbott*, 2020 WL 7042891, at *6 (same, and also distinguishing
5 *Roche v. CEPHEID*).⁵

6 There is no dispute that the claims of the '273 and '257 Patents are method-of-
7 preparation claims: the two independent claims are for "[a] method for making
8 Rebaudioside X" and "[a] method for adding at least one glucose unit to a steviol
9 glycoside substrate to provide a target steviol glycoside," and that language is
10 incorporated into all of the dependent claims. Unlike the cases cited by SweeGen,
11 the invention of the '273 and '257 Patent is not the discovery of a natural
12 phenomenon. Instead, the invention derives from the inventors' discovery that
13 Rebaudioside M, when analyzed in taste tests, has a superior taste profile in foods.
14 (PAMF 34.) At the time of filing, Rebaudioside M was not even known to exist in
15 the natural *Stevia rebaudiana* Bertoni plant. (PAMF 35.) PureCircle's discovery of
16 Rebaudioside M's superior taste profile led to the development of a method to
17 generate Rebaudioside M from stevioside and Rebaudioside A—the two most
18

19 _____
20 claim an improvement upon an existing medical process [B]ecause they are
21 directed to an improvement in the functionality of a useful device and process, I
22 conclude that they are not directed to patent-ineligible subject matter."); *Abbott*
23 *Labs. v. Grifols Diagnostic Sol'ns, Inc.*, 2020 WL 7042891, at *6 (N.D. Ill. Dec. 1,
24 2020) ("This makes claim 7 more akin to a method claim directed to the preparation
25 or production of something, like the claims the Federal Circuit found patent eligible
26 at step one in *Illumina* and *CellzDirect*."); *Natera, Inc. v. ArcherDX, Inc.*, 2020 WL
27 6043929, at *5 (D. Del. Oct. 13, 2020) ("As the Federal Circuit recently held in
28 *Illumina*, a patent directed to a method of preparation that exploits and does not
otherwise claim a natural phenomenon is patent eligible.").

⁵ SweeGen also ignores the Supreme Court's opinion regarding bioengineered materials like those in the PureCircle patent claims. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590-91 (2013) (claims for using bacteria containing plasmids to degrade oil were patent-eligible).

1 abundant steviol-glycosides in the plant—by using genetic engineering and
2 recombinant enzymes, despite prior art that insisted that Rebaudioside M could not
3 be made in this way. (PAMF 36.) None of these discoveries concerns a natural
4 phenomenon, and as described above, the claims include several limitations that do
5 not and cannot occur in nature.⁶ SweeGen's motion should be denied.

6 **III. THE '273 AND '257 PATENT CLAIMS SATISFY THE WRITTEN**
7 **DESCRIPTION REQUIREMENT**

8 SweeGen's motion for summary judgment based on the written description
9 defense suffers from at least two fatal flaws. First, PureCircle's patent claims at issue
10 in this case are based on the original claims in PureCircle's patent application, and
11 the law is clear that original claims can provide their own written description.
12 Indeed, the PTAB specifically rejected this same written description invalidity
13 argument in denying SweeGen's post-grant review ("PGR") petition regarding the
14 '257 Patent based on the original claims. SweeGen's motion fails to even argue,
15 much less prove, that any exception to the original-claim doctrine is present in this
16 case. To the contrary, SweeGen's expert (Dr. Gervay-Hague) conceded at her
17 deposition that PureCircle's expert's (Dr. Bollinger) original claim analysis was
18 correct. (PSUF 1.) Not only should SweeGen's motion for summary judgment on
19 written description be denied for this reason, but summary judgment that the claims
20 satisfy the written description should be granted in PureCircle's favor that the claims
21 satisfy the written description requirement since the original-claim doctrine can be
22 applied as a matter of law.

23 Second, SweeGen's motion should be denied because it is based on a
24 misapplication of the facts and the law. Specifically, SweeGen contends that
25

26 ⁶ SweeGen also cites *Biogen MA Inc. v. EMD Serono*, 976 F.3d 1326, 1332, 1334-
27 35 (Fed. Cir. 2020), a case having nothing to do with § 101 patent eligibility, and
28 *Genetic Veterinary Scis., Inc. v. LABOKLIN GMBH*, 933 F.3d 1302, 1319 (Fed. Cir.
2019), another case concerning diagnostic-testing claims.

1 because it purportedly uses a different pathway and a different enzyme from the
2 example enzyme in the PureCircle patents, and because the shared specifications of
3 the Patents do not describe the pathway or enzyme that SweeGen purportedly uses,
4 the claims must be invalid under the written description requirement. SweeGen also
5 posits that large numbers of UDP-glucosyltransferases could be made by mutating
6 the claimed UDP-glucosyltransferase enzymes, and the patent does not describe
7 (except as a general structural class) the specific sequences of this enormous set of
8 mutant enzymes. Dkt. No. 179-1 at 20. But the law has never required a patent to
9 describe all potential methods of practicing the claimed invention (including
10 examples that did not even exist at the time of filing) or all members of a class in
11 order for a claim to satisfy the written description requirement. Instead, the law only
12 requires that a patent specification describe examples of embodiments available at
13 the time of filing. SweeGen's argument that the '273 and '257 Patent claims are
14 invalid because their specifications do not describe SweeGen's alleged process of
15 making Rebaudioside M, is contrary to the law, raises genuine issues of disputed
16 material fact, and cannot support summary judgment of invalidity. SweeGen's
17 motion should be denied.

18 **A. The Claims Of The PureCircle Patents Are Original Claims That**
19 **Satisfy The Written Description Requirement**

20 "Original claims are part of the specification and in many cases will satisfy
21 the written description requirement." *Crown Packaging Tech. v. Ball Metal*
22 *Beverage*, 635 F.3d 1373, 1380 (Fed. Cir. 2011); *see also Mentor Graphics Corp. v.*
23 *EVE-USA, Inc.*, 851 F.3d 1275, 1297 (Fed. Cir. 2017) (reversing summary judgment
24 for failure to satisfy the written description requirement and finding that the original
25 claim was sufficient written description; "original claim language clearly
26 demonstrate[d] that the inventor possessed [the claimed] invention"); *In re Koller*,
27 613 F.2d 819, 823 (CCPA 1980) ("[O]riginal claims constitute their own
28 description.")). While there may be a limited exception to the original-claim

1 doctrine for "claims to a functionally defined genus," *Crown*, 635 F.3d at 1380, the
2 '273 and '257 Patent claims are not such claims because they claim structural
3 components: Rebaudioside M, steviol glycosides, and UDP-glucosyltransferases.
4 Since the original claims from March 12, 2013 (when the patent application was
5 filed) provide a written description for the claims at issue in the '273 and '257
6 Patents, SweeGen's written-description defense fails as a matter of law.

7 SweeGen's motion does not even address the original-claim doctrine, which is
8 surprising since Dr. Bollinger addressed that issue extensively in his report, and the
9 PTAB rejected SweeGen's '257 Patent PGR petition that raised this same written
10 description argument in part because of the original-claim doctrine. (PAMF 10.) In
11 his expert report, Dr. Bollinger demonstrated how original claims 5 and 20 in
12 PureCircle's May 2013 patent application correspond limitation-by-limitation to
13 claim 1 of the '257 Patent. (PSUF 3.), Dr. Bollinger also explained why this
14 comparison also showed that claim 1 of the '273 Patent was also disclosed in the
15 original claims. (PSUF 4.) Moreover, Dr. Bollinger also explained why all the
16 limitations in the '257 and '273 Patent claims—"Rebaudioside X," "Rebaudioside
17 D," UDP-glucosyltransferase," "conversion ... at least about ____ % complete,"
18 "adding at least one glucose unit," "steviol glycoside substrate," "target steviol
19 glycoside," "recombinant biocatalyst protein enzyme, and "UGT761"—are
20 structural limitations, not functional limitations. (PSUF 5.) He further explained
21 why the claimed "UDP-glucosyltransferases"—as opposed to the larger class of
22 "UDP-glycosyltransferases"—is a small class of enzymes consisting of just 12
23 known enzymes as of the priority date for PureCircle's patents, only 5 of which were
24 known to be active. (PSUF 6.) He also explained that the common structural
25 elements of these enzymes had already been depicted in the literature, (PSUF 7),
26 and he detailed the nature of their common structural features, (PSUF 8.) Dr.
27 Bollinger further explained how other enzymes that are not UDP-
28 glucosyltransferases also add glucose units to steviol glycosides, but because these

1 enzymes do not share UDP-glucosyltransferases' structural features, they are not
2 UDP-glucosyltransferases. (PSUF 9.) To the extent SweeGen presents evidence
3 disputing Dr. Bollinger's opinions, these are at a minimum factual issues that
4 preclude summary judgment in SweeGen's favor.

5 However, Dr. Gervay-Hague does not actually dispute Dr. Bollinger's
6 original-claim opinions or any of the underlying facts. She testified that the original
7 claims match up with the issued claims, and that she had no disagreement with Dr.
8 Bollinger in that respect. (PSUF 10.) Dr. Gervay-Hague also agreed that all terms in
9 the claim are structural. (PSUF 11.) And she agreed that enzymes other than UDP-
10 glucosyltransferases can add glucoses to the C-19 of steviol glycosides, (PSUF 12),
11 thus confirming Dr. Bollinger's opinion that UDP-glucosyltransferases are a specific
12 type of enzyme, and not just any enzyme that can add glucose. *See also* PSUF 13
13 (Dr. Gervay-Hague identified no issue working with a small number of enzymes,
14 such as the known 12 UDP-glucosyltransferases).

15 Thus, the experts are in agreement that the requirements of the original-claim
16 doctrine are met. Under these circumstances, the Court should not only deny
17 SweeGen's motion, but should grant summary judgment in favor of PureCircle and
18 find that the claims of the '257 and '273 Patent satisfy the written description
19 requirement as a matter of law. *Crown*, 635 F.3d at 1383 ("we reverse and enter
20 judgment for Crown on its cross-motion").

21 SweeGen relies on four cases for its written-description argument: *Idenix*,
22 *Juno*, *AbbVie*, and *Ariad*. Dkt. 179-1 at 18-19.⁷ Of the four, only one, *Ariad*,
23 addresses original claims. But the original-claim doctrine still applies after the *Ariad*
24 decision, which merely held that "certain claims, such as claims to a functionally
25

26 ⁷ Citing *Idenix Pharms. LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir.
27 2019); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021);
28 *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285 (Fed. Cir.
2014); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1371 (Fed. Cir. 2010).

1 defined genus, will not satisfy the written description requirement without a
2 disclosure showing that the applicant had invented species sufficient to support the
3 claims." *Crown*, 635 F.3d at 1380 (citing *Ariad*, 598 F.3d at 1349); *see also Mentor*,
4 851 F.3d at 1297 ("The very language of claim 1 which the court held was not
5 supported by the specification was present in the originally-filed claims. Original
6 claims are part of the original specification and in many cases will satisfy the written
7 description requirement."); *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989,
8 998 n.4 (Fed. Cir. 2000) ("One of this court's predecessor courts clarified that
9 disclosure in an originally filed claim satisfies the written description
10 requirement.").⁸ Here, the '273 and '257 Patent claims are not claims to a
11 functionally defined genus: they are structural claims subject to the original-claim
12 doctrine, and as the PTAB found in rejecting SweeGen's PGR petition, satisfy the
13 written-description requirement for that reason. (PAMF 10.)

14 Although SweeGen never addresses the original-claim doctrine in its brief, it
15 appears to argue that the claim term "UDP-glucosyltransferase" has somehow been
16 converted to a functional term in the '273 and '257 Patents based on the Court's
17 construction of "UDP-glucosyltransferase" as a "[a] *type of enzyme* that is capable
18 of transferring a glucose unit from a uridinediphosphate glucose molecule to a
19 steviol glycoside molecule." Dkt. No. 143 at 2-3 (emphasis added). SweeGen's
20 argument fails because it ignores the phrase "a type of enzyme that is capable of,"
21 which arises from the specification language "[t]he UDP-glucosyltransferase can be
22 any UDP-glucosyltransferase capable of adding at least one glucose unit to the
23 steviol glycoside substrate to provide the target steviol glycoside." (Dkt. 180-2 '273
24 Patent Col.2 ll.40-43 & Col.8 ll.29-32.) This "type of enzyme that is capable of ..."

26 ⁸ For district court cases, *see, e.g., Sunoco Partners Mktg. & Terms. L.P. v. Powder*
27 *Springs Logs., LLC*, 2020 WL 1234822, at *6 (March 13, 2020); *PerDiemCo v.*
28 *IndusTrack LLC*, 2016 WL 6662865, at *3 (E.D. Tex. Oct. 28, 2016); *Bristol-Myers*
Squibb Co. v. Mylan Pharms Inc., 2013 WL 12322088, at *17 (Oct. 17, 2013).

1 language set forth in the Court's claim construction restricts the claim UDP-
2 glucosyltransferases to those UDP-glucosyltransferase enzymes that can carry out
3 the specific reaction of transferring a glucose unit from a uridinediphosphate
4 glucose molecule to a steviol glycoside molecule. Contrary to SweeGen's
5 suggestion, the Court's construction does not eliminate the requirement that the
6 claimed enzyme must be the type of enzyme known as a "UDP-glucosyltransferase."

7 This language in the Court's construction distinguishes this case from the
8 *Idenix* case cited by SweeGen (Dkt. 179-1 at 21-23), where the patent owner argued
9 that the claims should be limited to "candidates [that] were likely to inhibit
10 NS5B..." *Idenix*, 941 F.3d at 1158. The Federal Circuit held that "[t]his argument
11 improperly attempts to narrow the claim to only those nucleosides that would inhibit
12 the NS5B polymerase," "[b]ut the district court's claim construction ... made clear
13 that 'as a matter of law, NS5B activity is *not* a claim limitation.'" *Id.* at 1158-59
14 (emphasis in original). By contrast, the Court's construction requiring the UDP-
15 glucosyltransferase to be "a type of enzyme capable of transferring a glucose unit
16 from a uridinediphosphate glucose molecule to a steviol glycoside molecule" means
17 that the enzyme must be in the class of UDP-glucosyltransferase enzymes and must
18 also be able to transfer a glucose unit. This language does not take away from the
19 fact that UDP-glucosyltransferases are a type of enzyme having a common structure.

20 It is undisputed that there were only 5 UDP-glucosyltransferases at the time
21 of filing that were known to be capable of transferring a glucose unit. (PSUF 14)⁹
22 The only reason that those 5 UDP-glucosyltransferases can now be amplified by
23 SweeGen to allege there are billions of UDP-glucosyltransferases is that the genetic
24 sequence of those 5 UDP-glucosyltransferases can be slightly altered in many
25 different ways to form mutants. But mutants are not an unlimited structural class:

26
27 ⁹ SweeGen also asserts that the number is 4 UDP-glucosyltransferases. Dkt. 179 at
28 25 (citing SUF 71). Whether the number is 4, 5, or 12 is immaterial to the argument
here, so long as the number is small.

1 after all, the reason they are called "mutants" is that they are minor adjustments
2 based on the original wild-type enzymes (PSUF 15), homology modelling can show
3 which mutants will be most active (PSUF 16), and the vast majority of mutants were
4 shown to be active ((PSUF 17) & Dkt. 179-2 at 27-28 (SweeGen's SUF 73).) Thus,
5 SweeGen's rhetorical inflation of the 5 known UDP-glucosyltransferases into
6 billions of potential mutants does not change the fact that the UDP-
7 glucosyltransferases are a structural class. "For chemical compounds, the written
8 description requirement is satisfied when the application discloses 'relevant
9 identifying characteristics' such that the compound can be distinguished from other
10 compounds." *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, 2013 WL 12322088,
11 at *17 (D. Del. Oct. 17, 2013). Indeed, SweeGen identifies the variations it relies on
12 its motion as "UDP-glucosyltransferase mutants," Dkt. 179-1 at 19-20, which itself
13 distinguishes these molecules from other compounds.

14 Applying SweeGen's rationale outside the context of the claims at issue here
15 underscores why SweeGen's argument is contrary to both the law and common
16 sense. For example, a claim may have a limitation requiring "a chair," and that term
17 may be construed for that claim as "a type of chair that is capable of supporting an
18 adult." Chairs can come in all kinds of sizes, have any number of legs, may or may
19 not include cushions, and can be made of many materials. The mutations or
20 variations on a chair are limitless. But just as not all UDP-glucosyltransferases will
21 be capable of transferring a glucose unit, not all chairs will be capable of supporting
22 an adult. On the flip-side, not all things capable of supporting an adult will be chairs.
23 But that does not mean that the chair patent would be invalid for failure to satisfy
24 the written description because the specification did not describe the limitless
25 number of variations of chairs, both in existence at the time of filing and to be made
26 in the future. That is because "a type of chair that is capable of supporting an adult"
27 is a structural element, just like a UDP-glucosyltransferase capable of transferring a
28 glucose unit is a structural element.

1 SweeGen also asserts that the structure of UDP-glucosyltransferases was
2 unknown in May 2012. Dkt. 179-1 at 24. But that is not true, and it creates a dispute
3 of fact that precludes summary judgment. As Dr. Bollinger explained, the structure
4 of UDP-glucosyltransferases capable of adding glucose units had been determined
5 by modelling based upon the known crystal structures of several UDP-
6 glucosyltransferases. (PSUF 18.) Indeed, crystal structures of many UDP-
7 glucosyltransferases had been determined in the prior art, including prior-art patents
8 that SweeGen has separately argues renders PureCircle's patents obvious. (PSUF 19,
9 Gervay-Hague Dep. 13:1-7.) And as Dr. Gervay-Hague testified, the structure of
10 UDP-glucosyltransferases is "conserved," despite changes in the amino-acid
11 sequence, which means that the structure was known. (PSUF 20.) Indeed, Dr.
12 Gervay-Hague's obviousness opinions (that persons of skill would have known that
13 UDP-glucosyltransferases could be used to prepare Reb M) are at odds with her
14 written description opinion (that persons of skill in the art would have even known
15 the structure of a UDP-glucosyltransferases), and her obviousness testimony
16 identifies several other disputed issues of fact that require denying SweeGen's
17 written description motion. (*See, e.g.*, PAMF 65) (known crystal structures of the
18 claimed UDP-glucosyltransferases); (PAMF 66) (UDP-glucosyltransferases are a
19 known structural class and "it's known how to discover glucosyltransferases").

20 Unlike the cases that SweeGen relies upon, the '273 and '257 Patent claims
21 have structural limitations and meet the written description requirement because
22 they stem from an original claim, just as the PTO found in rejecting SweeGen's PGR
23 petition. (PSUF 2.) Thus, not only should SweeGen's motion be denied, but the
24 Court should grant summary judgment that the '273 and '257 Patent claims satisfy
25 the written description requirement as a matter of law.

26 **B. The Law Does Not Require PureCircle to Describe Future Versions**
27 **of the Invention**

28 The gravamen of SweeGen's argument is that the '273 and '257 Patents do not

1 describe all mutants and all fusion enzymes "including those yet to be discovered."¹⁰
2 Dkt. 179-1 at 21; *see also* PSUF 21. SweeGen also faults the Patents for not
3 disclosing how to make Rebaudioside M through Rebaudioside D4, which
4 according to SweeGen, "Reb D4 was unknown as of the priority date of the asserted
5 patents."¹¹ *Id.* at 5. But the law does not require patent applicants to describe items
6 yet to be discovered, or to enable them. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d
7 1336, 1344 (Fed. Cir. 2001) ("Our case law is clear that an applicant is not required
8 to describe in the specification every conceivable and possible future embodiment of
9 his invention.").

10 Instead, "application sufficiency under § 112, first paragraph [written
11 description and enablement requirements], must be judged as of the filing date."
12 *U.S. Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989)
13 (internal quotations omitted). Thus, the fact that a "claim may cover a later version
14 of the claimed composition" does not affect patentability, because "[t]o hold
15 otherwise would... 'impose an impossible burden on inventors and thus on the
16 patent system.'" *Id.* at 1251-52 (quoting *In re Hogan*, 559 F.2d 595, 606 (CCPA
17 1977)).¹² Simply put, the law does not require PureCircle to describe all future

18
19 ¹⁰ A "fusion enzyme" is a just an enzyme with something else attached ("fused") to
20 it. (PAMF 38.) [REDACTED]

21 [REDACTED]
22 [REDACTED]
23 [REDACTED] For the same reasons described herein, SweeGen's fusion
24 enzyme argument is contrary to the law because a patent does not need to describe
25 *all* potential embodiments.

26 ¹¹ [REDACTED]
27 [REDACTED]
28 [REDACTED] *See* Dkt. 168-1 (Opening Br. Re § 295) at 6-10.

¹² The CCPA is the predecessor court to the Federal Circuit, and its decisions are

1 methods of practicing the claimed invention (or materials that could be used to do
2 so) that had not yet been discovered. *See Hormone Res. Found'n, Inc. v. Genentech,*
3 *Inc.*, 904 F.2d 1558, 1568 (Fed. Cir. 1990) ("Merely because purer and more potent
4 forms of the ... compound might be produced using later-discovered technology
5 does not necessarily mean that the ... patent specification did not provide sufficient
6 enabling disclosure as of the filing date of the invention."); *Amgen Inc. v. Hoechst*
7 *Marion Roussel, Inc.*, 314 F.3d 1313, 1331-32 (Fed. Cir. 2003) ("The written
8 description inquiry, therefore, focuses on a comparison between the specification
9 and the invention referenced by the terms of the claim — not comparison between
10 how the product was made as disclosed in the patent and future developments of this
11 process that might alter or even improve how the same product is made."). Thus,
12 SweeGen's written description and enablement defenses—both of which are based
13 in part on the absence of disclosure showing how to make later-developed Reb D4
14 or fusion enzymes—is incorrect as a matter of law.

15 SweeGen's written description argument misapplies the decisions in *AbbVie*,
16 *Ariad*, *Idenix*, and *Juno*. Dkt. 179-1 at 18-19, 21. These cases concern claims having
17 limitations that are purely functional, not structural limitations like "UDP-
18 glucosyltransferase." The *AbbVie* claims recited anything that "binds to human IL-
19 12 and dissociates from human IL-12," *AbbVie*, 759 F.3d at 1292, the *Ariad* claims
20 recited anything "reducing NF- κ B activity in the cells," *Ariad*, 598 F.3d at 1341, and
21 the *Juno* claims recited "a binding element that specifically interacts with a selected
22 target," with no limit on what a binding element or target was, *Juno*, 10 F.4th at
23 1334. The *Idenix* case claims recited "any imaginable substituent at the 2'-down
24 position," which would effectively encompass all of chemistry, rendering the only
25 meaningful limitation "a method for the treatment of a hepatitis C virus infection."

26
27
28 considered to be Federal Circuit precedent unless overruled. *South Corp. v. United*
States, 690 F.2d 1368, 1369 (Fed. Cir. 1982).

1 *Idenix*, 941 F.3d at 1149. It is because the claims would cover any chemical "that
2 also happens to treat HCV" that the Federal Circuit remarked that the claims cannot
3 "cover any compound later actually invented and determined to fall within the
4 claim's functional boundaries," *id.* at 1164-65. But that is not the case for a term like
5 "UDP-glucosyltransferase," which is structural, and where there were only 12
6 known UDP-glucosyltransferases—5 of which were active—at the time of filing.

7 SweeGen also argues that of the 12 known UDP-glucosyltransferases, only 3
8 out of 12 were found to be active. Dkt. 179-1 at 25. SweeGen's arguments fails to
9 raise any written description issue. Indeed, SweeGen's argument is based on a paper
10 referenced in the '273 and '257 Patents and published in 2005—seven years before
11 the May 22, 2012 priority date of these patents—and thus does not limit what those
12 of skill in the art knew in May 2012. Dkt. 179-1 at 25. Moreover, rather than
13 showing an issue with written description, this prior-art knowledge shows how easy
14 screening these molecules was, and that the universe of UDP-glucosyltransferases in
15 2012 was quite confined. SweeGen's argument thus supports PureCircle's position.

16 Finally, SweeGen points to a factual disagreement between PureCircle's
17 expert and SweeGen's expert regarding how effective homology modelling was in
18 identifying those UDP-glucosyltransferase mutants which are capable of transferring
19 a glucose. (Dkt. 179-1 at 24; PAMF 58.) That factual disagreement cannot support
20 summary judgment. Moreover, contrary to SweeGen's suggestion, there is no
21 dispute that mutants and how to make them were known in the prior art. (PSUF 22
22 Bollinger Rebuttal Report ¶¶ 298-299). Indeed, even SweeGen's former expert, Dr.
23 Walters, agrees that such claims were appropriate in 2012 because mutants "were
24 reasonably expected to catalyze the conversions." ((PSUF 23) (quoting the Walters
25 Dep. 126:22-127:8).) At a minimum, there are genuine issues of material fact that
26 preclude summary judgment based on written description.

27 In sum, SweeGen's written description (and enablement) challenge rely on the
28 absence of disclosure of later technology—fusion enzymes and Reb D4—but the

1 law does not require later technology to be described in a patent specification, since
2 that would be impossible. That is why the PTAB found that SweeGen's nearly
3 identical written description arguments in its PGR petition failed to satisfy the lower
4 standard of proof in PGR proceedings as compared to the clear and convincing
5 evidence standard that SweeGen must satisfy on this motion. (PAMF 59.) Indeed,
6 the PTAB determined "that a person of ordinary skill in the art could envision the
7 steviol glycosides and UDP-glycosyltransferases encompassed by the claims
8 because they have common structural features," and found that the claims of the
9 '257 Patent (which shares an identical specification to the '273 Patent) satisfied the
10 written description requirement. (PAMF 11.) This Court should do the same, and
11 SweeGen's motion based on the written description requirement should be denied.

12 **IV. THERE ARE MANY DISPUTED ISSUES OF FACT THAT**
13 **PRECLUDE SUMMARY JUDGMENT REGARDING ENABLEMENT**

14 SweeGen's motion for summary judgment regarding the enablement
15 requirement (35 U.S.C. § 112) is without merit for at least three reasons: (1) it
16 misconstrues the law of enablement, which only requires disclosure of one mode of
17 making and using the invention; (2) it provides virtually no factual analysis and only
18 attorney argument regarding most of the eight *Wands* factors, most of which are
19 hotly disputed by the parties; and (3) like its written description defense, SweeGen
20 imports a requirement that the '273 and '257 Patents enable later-developed
21 technology. For these reasons, SweeGen's motion for summary judgment seeking to
22 invalidate the '273 and '257 Patent's claims should be denied.

23 **A. The Specification Need Only Enable One Mode Of Carrying Out**
24 **The Invention, Not Every Possible Mode Of Doing So**

25 "Enablement does not require the inventor to foresee every means of
26 implementing an invention at pains of losing his patent franchise. Were it otherwise,
27 claimed inventions would not include improved modes of practicing those
28 inventions. Such narrow patent rights would rapidly become worthless as new

1 modes of practicing the invention developed, and the inventor would lose the benefit
2 of the patent bargain." *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d
3 1052, 1071 (Fed. Cir. 2005). Instead, "[t]he enablement requirement is met if the
4 description enables any mode of making and using the invention." *Id.* (quoting
5 *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998).

6 The '273 and '257 Patents are directed to methods of preparing or making
7 Rebaudioside M—a compound discovered by the inventors for the first time to be
8 valuable. (PAMF 6.) The patents do not purport to have invented UDP-
9 glucosyltransferases. (*Id.*) UDP-glucosyltransferases already existed in the prior art,
10 and were already used to make other steviol glycosides, including the precursor
11 Rebaudioside D. (PAMF 60) (quoting SweeGen's former expert, Dr. Olsson, who
12 testified that using UDP-glucosyltransferases ("UGTs") was "well-understood,
13 routine, and conventional in the art.".) The new method claimed in the '273 and
14 '257 Patents uses the known enzymes—UDP-glucosyltransferases—as a tool to
15 make Rebaudioside M. (PAMF 61.) And the 20 examples in the patent specification
16 show how to create microorganism hosts that produce UDP-glucosyltransferases in
17 order to make Rebaudioside M from other steviol glycosides by adding glucose
18 units. (PAMF 62.) None of these facts are disputed.

19 Several modes of carrying out the invention, using the steviol glycosides and
20 UDP-glucosyltransferases described in the '273 and '257 Patent specifications, are
21 detailed in the patents. (*Id.*) Indeed, SweeGen does not argue that the Patents fail to
22 enable a mode of making Rebaudioside M by using UDP-glucosyltransferases, but
23 rather, that the patents provide no guidance on how to find new UDP-
24 glucosyltransferase enzymes that would fall within the claims, and that it is not
25 known how to find new enzymes capable of the Rebaudioside-D-to-Rebaudioside-
26 M conversion claimed in the '273 Patent's claims. (PAMF 45.) As an illustration, Dr.
27 Gervay-Hague points to a new UDP-glucosyltransferase discovered in 2020 called
28 "UGT-76" (pronounced "UGT dash 76") (which is different from the UGT76G1

1 enzyme claimed in the Patents), and argues that since UGT-76 was not created until
2 2020, that particular enzyme could not be described in May 2012 when the '273 and
3 '257 Patents were filed, and thus the claims are not enabled because "the patent
4 provides no guidance on how to find this enzyme." (PAMF 63.)

5 But the law does not support SweeGen's argument that "undue
6 experimentation would be required for one artisan to synthesize all members of the
7 genus of" UDP-glucosyltransferases that could carry out the invention: "That is not
8 the correct inquiry." *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F.
9 Supp. 3d 629, 661 (E.D. Tex. 2017) (Bryson, Fed. Cir. J, by designation), *aff'd* 739
10 F. App'x 643 (Fed. Cir. 2018). Rather, the law requires only that the patents describe
11 at least one mode of carrying out the invention using technology available at the
12 time of filing, and a patent "does not need to ensure that a skilled artisan can
13 practice the entire scope of the invention within a short period." *Id.* There is no
14 dispute that the '273 and '257 Patents include real experiments that made
15 Rebaudioside M using the claimed methods. (PAMF 8 (citing working examples 6,
16 13, & 14); Pollack Decl. Ex. 2 ('257 Patent) cols. 20-30.)

17 That the Patents function with a broad range of UDP-glucosyltransferases is
18 not the issue: it is the method of making Rebaudioside M that must be enabled here,
19 not the "genus" of all UDP-glucosyltransferases. *Cf. Dako*, 2009 WL 1083446, at
20 *9; *In re Biogen Patent Litig*, 2018 WL 3586271, at *7 (D.N.J. July 26, 2018) ("the
21 Court finds that it is not the genus of expression systems that must be enabled and
22 described, it is the method of treatment that must be enabled and described."). As in
23 *Dako*, SweeGen "either fails to appreciate or intentionally disregards the pivotal
24 distinction between a product claimed qua product versus a component claimed as
25 part of a method." *Dako*, 2009 WL 1083446, at *10.

26 In fact, in *Biogen*, *Dako* and *UroPep*, the defendants made the same argument
27 that SweeGen makes here—that a tool for carrying out the invention (hosts making
28 recombinant proteins in *Biogen*, probes in *Dako*, PDE5 inhibitors in *UroPep*) were a

1 large class but not all species within that class were described. *Id.*; *UroPep*, 276 F.
2 Supp. 3d at 646 (alleging "billions of compounds"); *Biogen*, 2018 WL 3586271 at
3 *8 ("millions of species ..." but "the specification discloses production of such
4 polypeptides in only two species ... of hosts"). But the *Biogen*, *Dako* and *UroPep*
5 courts rejected those arguments, because the invention was not the polypeptides,
6 probes and PDE5 inhibitors, but the claimed methods for using those known
7 materials to reach the desired result. *UroPep*, 276 F. Supp. 3d at 647-48 ("PDE5
8 inhibitors were not themselves the invention... [I]nstead, the invention was to use a
9 group of compounds well known in the art ... in a novel method of treating BPH.").
10 Similarly, in *Invitrogen*, the claims covered a mutated enzyme, without regard to the
11 method used to create the mutation. 429 F.3d at 1070. The patent described mutation
12 by deletion mutation, but not by point mutation. *Id.* Because the claims covered
13 either mutation method, the defendant argued that they were non-enabled. *Id.* The
14 Federal Circuit disagreed and held the enablement requirement satisfied. *Id.* at 1071.

15 Here, the invention in the Patents is not UDP-glucosyltransferases, which
16 were known: the invention is bioengineering and using these enzymes to make Reb
17 M. The patents undeniably disclose how to make Reb M using the method in the
18 claims. The patents do not need to disclose every possible way of doing so. Thus, as
19 articulated in *Invitrogen*, *UroPep*, and *Dako*, because the '273 and '257 Patent
20 specifications disclose modes of practicing the invention, the claims are enabled.

21 **B. SweeGen's Analysis of the Detailed Eight-Factor *Wands* Test is Far**
22 **Too Superficial to Support an Enablement Defense**

23 Enablement entails many factual aspects, including the factual inquiries
24 required by the eight-factor test set forth in *In re Wands*, 858 F.2d 731, 737 (Fed.
25 Cir. 1988) cited by SweeGen. Dkt. 179-1 at 26. Here, extensive expert testimony
26 from Dr. Bollinger that a person in ordinary skill in the art would know how to
27 make and use the claimed invention gives rise to numerous factual questions
28 precluding summary judgment of that the claims are not enabled.

1 The only *Wands* factor that SweeGen analyzes in detail confirms that there
2 are disputed issues of fact preventing summary judgment. In addressing the quantity
3 of experimentation factor, SweeGen contends that Dr. Bollinger and Dr. Prakash (a
4 co-inventor) admitted that "a skilled artisan would have had to discover and analyze
5 millions of candidate enzymes," citing SUF 73. Dkt. 179-1 at 26. But Dr. Bollinger
6 and Dr. Prakash admitted no such thing. SweeGen's SUF 73 states: "As shown from
7 [SweeGen's former expert] Dr. Olsson's results in his Figure 5, the vast majority of
8 the mutants he prepared and tested produced Rebaudioside M. His paper thus proves
9 that, even though there are many mutations that can theoretically be made in
10 UGT76G1, a large fraction of the resulting mutants will be still active." Dkt. 179-2
11 at 27-28 (SUF 73). But as Dr. Bollinger explained, this fact shows enablement, not
12 non-enablement, because it proves that most mutants are active and will work with
13 the invention. (PAMF 54.) Moreover, the evidence cited by SweeGen says nothing
14 admitting that "millions of candidate enzymes" would need to be analyzed. The
15 remaining SUFs SweeGen relies upon for this factor (SUFs 66-68, 78-80) are
16 similarly mischaracterized, and both Dr. Bollinger and Dr. Walters (another of
17 SweeGen's former experts) agree that homology modeling can be used to screen out
18 poorly performing mutants. (PAMF 64). Only Dr. Gervay-Hague disagrees, but that
19 disagreement only underscores why summary judgment should be denied.

20 Dr. Gervay-Hague's admissions regarding this *Wands* factor further support
21 PureCircle's position, and demonstrate why summary judgment would be improper.
22 When confronted with the evidence regarding homology modeling, Dr. Gervay-
23 Hague confirmed that homology modeling and software used to perform it was
24 available in May 2012. (PAMF 47). She also agreed that Drs. Olsson and Simon-
25 Vecilla—two inventors of a patent making Reb M using UDP-glucosyltransferase
26 filed 1 year *after* PureCircle (and thus, too late to claim this invention)—used
27 homology modelling in 2013 to locate the appropriate small set of mutants
28 worthwhile further to analyze with experimental testing. (PAMF 48, PAMF 49).

1 Moreover, Dr. Gervay-Hague admitted that Dr. Simon-Vecilla screened
2 thousands of UDP-glucosyltransferase mutants for mutants that could convert
3 Rebaudioside A to Rebaudioside D by using homology modelling, that this
4 homology modeling was performed before the Patents' May 2012 filing date, and
5 that experimentation he performed to identify and test approximately 1600 mutants
6 was performed in a reasonable timeframe. (*Id.* 24:2-24, 24:25-28:1.) Thus, the
7 evidence shows not only that homology modelling could be used to screen mutants
8 in May 2012, but that in fact, this was done and the results were reported. And
9 although Dr. Gervay-Hague was in direct communication with Dr. Simon-Vecilla
10 (who is a current Conagen employee who worked with SweeGen's experts in this
11 case) in connection with this lawsuit, she never asked him how long it took him to
12 perform the experiments on the 1600 mutants, even though SweeGen bears the
13 burden of proof on the issue of whether the experimentation would be undue. (*Id.*
14 27:7-28:1). Contrary to SweeGen's arguments, there is a significant factual dispute
15 regarding whether homology modeling followed by testing could be practically used
16 in May 2012 to enabled the claimed invention. Indeed, the PTAB—reviewing
17 virtually the same evidence in connection with SweeGen's PGR petition, rejected
18 SweeGen's enablement argument and found that homology modelling would be
19 used to select the appropriate mutants. (PAMF 56.) The PTAB's decision further
20 underscores why summary judgment is not appropriate on the issue of enablement.

21 For the remaining seven *Wands* factors, SweeGen relies almost entirely on
22 attorney argument. Dkt. 179-1 at 27-30. Needless to say, Dr. Bollinger disagrees
23 with SweeGen's positions and has articulated why the remaining *Wands* factors
24 support a finding that the claims of the '273 and '257 Patents are enabled. (PAMF
25 55.) Although SweeGen disagrees with Dr. Bollinger's opinions and the facts he
26 relies on, those disagreements demonstrate precisely why summary judgment should
27 be denied. Indeed, the PTAB performed a thorough analysis of the remaining *Wands*
28 factors—such as the high level of skill in the art and the extensive working

1 examples—in connection with SweeGen's PGR petition regarding the '257 Patent,
2 and found that the *Wands* factors support a finding of enablement. (PAMF 57.) That
3 same analysis is highly relevant to the claims of the '273 Patent, which shares the
4 same specification as the '257 Patent. The facts articulated by the PTAB have not
5 changed between the decision to deny SweeGen's PGR petition and the filing of
6 SweeGen's Summary Judgment Motion, nor does SweeGen make any effort to
7 address the PTAB's findings and conclusions.

8 In sum, there are many disputes regarding the facts that must be considered
9 under the eight-factor *Wands* test, and summary judgment is not appropriate.

10 **V. CONCLUSION**

11 SweeGen's motion for summary judgment should be denied. SweeGen's
12 patent ineligibility arguments misapply the law, fail to consider the claim as a
13 whole, and ignore several claim limitations that do not and cannot occur in nature.
14 SweeGen's written description and enablement arguments likewise overreach on the
15 law, and never meaningfully address the PTAB's rejection of those same arguments
16 under a significantly lower burden of proof than applies here. At a minimum, many
17 factual disputes prevent granting summary judgment on written description and
18 enablement, and SweeGen's failure to address the original-claim doctrine supports
19 granting summary judgment that the written description requirement is satisfied.
20 SweeGen's invalidity summary judgment motions should be denied.

21 Dated: March 14, 2022

DLA PIPER LLP (US)

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